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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,446	09/08/2000	David E. Edgren	ARC 2762C1	1540

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/657,446

Applicant(s)

EDGREN ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46, 51 and 54-60 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 46, 51 and 54-60 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment, remarks and declaration under 37 CFR 1.132, all filed 8/05/06. Claims 48 and 53 are canceled. Thus claims 46, 51, and 54-60 are pending.

Response to Arguments

1. Any previous rejections not reiterated herein are withdrawn.
2. Claims 46, 51 and 54-60 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bartoo et al. (US 4,743,248). Claims 48 and 53 were canceled by the amendment of 8/05/06.

Bartoo teaches an osmotic dosage form comprising an outside wall and an inside wall (abstract). The outside wall comprises semipermeable polymers where the semipermeable polymers are cellulose esters, cellulose ethers, cellulose acylate, cellulose acetate and cellulose diacetate and triacetate (column 3, line 54 to column 4 line 5). The inside wall comprises polymeric formulation that is responsive to environmental changes such as pH (column 4, lines 6-9). The internal compartment comprises beneficial agents or active drugs and the dosage form also has an expandable layer (column 4, lines 47-68; column 5, lines 49-55; and column 7, line 6). In example 1, the cores are coated with an inside wall forming composition comprising hydroxypropylmethylcellulose phthalate, cellulose acetate, sorbitol and polyethylene glycol; and a second outside semipermeable wall is coated onto to the inside wall. Cellulose acetate is insoluble. Hydroxypropylmethylcellulose phthalate is also insoluble. Sorbitol and polyethylene glycol are soluble. The foregoing has been admitted by applicant in the 1.132 declaration. The scope of the claims in the application read broadly on a conventional osmotic

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dosage form and reads on Bartoo. The generic claims 46 and 60 recite hydrophobic and hydrophilic substances. Sorbitol and polyethylene glycol are hydrophilic substances. Cellulose acetate and hydroxypropylmethylcellulose phthalate are hydrophobic substances. The dosage of Bartoo would be capable of the release profile recited in claims 55-58 of the application since the claimed dosage form reads on the dosage form of Bartoo. The claimed method, claim 60, is a broad administration of the claimed composition and Bartoo's dosage form is administered to animals meeting the administration method of claim 60. Osmotic dosage form contains osmotic core. Thus, Bartoo anticipates the claims.

Response to Arguments

Applicant argues that a) Bartoo does not disclose or teach that the hydrophilic substance included in the inside wall has an aqueous solubility that is sensitive to osmotic pressure and b) that applicant's 1.132 declaration shows that the hydrophilic substance hydroxypropylmethylcellulose phthalate is sensitive to pH changes and not to changes in osmotic pressure, that the hydrophilic polyethylene is insensitive to changes in pH and osmotic pressure, and that hydroxypropylcellulose, an hydrophilic substance, which is given as one of the examples in the instant application is responsive to osmotic pressure at a determined aqueous solubility.

3. Applicant's arguments filed 8/5/06 with respect to Bartoo have been fully considered but they are not persuasive.

Regarding a) it is noted that the dosage form of Bartoo has an exit or orifice that classifies the dosage form as an osmotic device. Secondly, Bartoo specifically discloses that one of the objects is to provide an "osmotic device shaped, sized, structured and adapted for the

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controlled and continuous delivery of a beneficial drug throughout the gastrointestinal tract” (column 2, lines 29-32). Thus, being an osmotic device, osmotic pressure gradient would be expected to develop inside the osmotic core. Furthermore, sorbitol is a known in the art of osmotic dosage forms to be an osmotic agent. Therefore, Bartoo does not have to specifically disclose that “the hydrophilic substance included in the inside wall has an aqueous solubility that is sensitive to osmotic pressure.”

Regarding b), it is noted that hydroxypropylcellulose is not recited in the claims and data leading to conclusion of sensitivity or non-sensitivity of sorbitol, polyethylene glycol and hydroxypropylmethylcellulose phthalate is not obtained in an environment of an osmotic dosage form. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The declaration is thus not commensurate with the claims.

The declaration under 37 CFR 1.131 by David E. Edgren:

4. The declaration under 37 CFR 1.132 filed 8/5/06 is insufficient to overcome the rejection of claims 46, 51 and 54-60 based upon reference applied under 35 USC 102 as set forth in the last Office action because:

The data in the declaration does not appear to be coming from empirical runs of osmotic dosage forms of the type disclosed in Bartoo. Specifically, applicant provides solution chemistry of cimetidine HCl in exhibit I where the osmotic pressure of saturated solution of cimetidine HCL is determined/measured; second, osmotic pressure of sorbitol solution in de-ionized water is determine/measured at 37 °C as a function of concentration as shown in exhibit

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II; third, solubilities of HPMCP, HPMC, polyethylene glycol, cellulose acetate, ethylcellulose and hydroxypropylcellulose in artificial intestinal fluid are determined as shown in exhibit III.

None of the exhibit is an osmotic dosage form, rather individual/single components are used in the determinations/measurements. The declaration is not commensurate with the claims.

No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

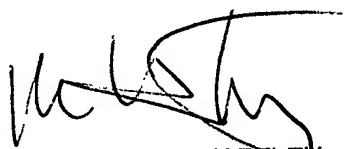
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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